

**Summary of Safety and Effectiveness Information**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMMA 1990 and 21 CFR 807.92.

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**Date of Preparation:** 6/28/96

**Name of Product:** aca® **plus** Free Thyroxine (FT4) Method

**FDA Classification Name:** Free Thyroxine Test System

**Predicate Device:** Abbott Laboratories IMX® Free T4

**Device Description:** The FT4 assay is a one-step competitive enzyme immunoassay. Patient sample is added by the aca® **plus** to a reaction vessel containing chromium dioxide particles coated with monoclonal antibodies specific for FT4 and T3-alkaline phosphatase conjugate reagent. A particle/FT4/ conjugate sandwich forms during an incubation period. The sandwich is washed to remove any unbound conjugate. The mixture is resuspended and the sandwich is transferred by the aca® **plus** to an FT4 test pack. The FT4 test pack is then placed into an aca® discrete clinical analyzer.

The bound alkaline phosphatase triggers an amplification cascade, resulting in the formation of a colored product. The color change measured at 510nm is directly proportional to the concentration of free thyroxine present in the patient sample.

**Intended Use:** The FT4 Method is used in the aca® **plus** immunoassay system to quantitatively measure free thyroxine (FT4) in human serum and heparinized plasma.

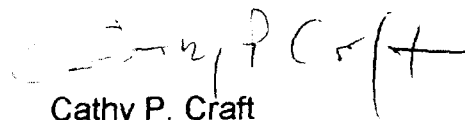
**Comparison to Predicate  
Device:**

<u>Item</u>	<u>aca® <i>plus</i> FT4</u>	<u>IMx® Free T4</u>
Technology	Competitive format monoclonal antibody immunoassay	Competitive format polyclonal antibody immunoassay
Detection	Colorimetric endpoint measurement at 510nm and 600nm	Fluorometric endpoint measurement

**Comments on Substantial**

**Equivalence:** Split sample comparison between the aca® *plus* FT4 Method and the Imx® Free T4 assay gave a correlation coefficient of 0.9076, slope of 0.94, and an intercept of 0.16 when tested with 146 clinical patient samples.

**Conclusion:** The aca® *plus* FT4 Method is substantially equivalent in principle and performance to the IMx® Free T4 Assay based on the split sample comparison discussed above.



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Date: